

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,992	KURODA, MASAHARU	
	<b>Examiner</b>	<b>Art Unit</b>	
	CATHY K. WORLEY	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on Jan. 21, 2010.
2. ☒ The allowed claim(s) is/are 1, 2, 4-9, 11, 12, 16, 19-21, 23-29, 31, 32, 34-38, 40-53, 55-61, 63, 65-67, and 77-87 ; renumbered as claims 1-64, respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>1279</u> .</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638



**ALLOWANCE**

- 1) The response filed on Jan 21, 2010, has been entered.

***REJOINDER***

- 2) Because the product claims were found to be allowable, and the linking claims were found to be allowable, all groups were rejoined with the exception of Groups V-VIII which remain restricted.

### EXAMINER'S AMENDMENT

3) An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan J. Myers Fitch on Feb. 4, 2010.

4) The application has been amended as follows:

#### IN THE CLAIMS:

Claims 3, 10, 13-15, 17, 18, 22, 30, 33, 39, 54, 62, 64, 68-76, and 88-91 are cancelled.

1. (Currently Amended) An isolated nucleic acid molecule having antisense or RNA interference activity comprising a promoter that functions in a rice plant operably linked to:

(i) a nucleic acid sequence having at least 15 contiguous nucleotides complementary to a gene encoding a rice prolamin polypeptide, or

(ii) a nucleic acid sequence having at least 70% homology to (i),

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wherein, when introduced into a rice cell expressing the prolamin polypeptide the nucleic acid is ~~introduced into a rice plant cell expressing the prolamin polypeptide,~~ and the antisense activity reduces effective for reducing the amount of expression of the prolamin polypeptide relative to a rice plant into which the nucleic acid was not introduced, ~~and wherein the nucleic acid is operably linked in antisense orientation to a promoter that functions in a rice plant.~~

7. (Currently Amended) The nucleic acid molecule according to claim 1, wherein the nucleic acid sequence having at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide is complementary to the sequence encoding the signal peptide of said prolamin ~~a 5' terminal nucleic acid sequence encoding the prolamin polypeptide.~~

8. (Currently Amended) The nucleic acid molecule according to claim 1, wherein the at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide is a polynucleotide length of 50 nucleotides or less.

9. (Currently Amended) The nucleic acid molecule according to claim 1, wherein the at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide is a polynucleotide length of 30 nucleotides or less.

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10. (Cancelled)

12. (Currently Amended) The nucleic acid molecule according to claim 1, ~~comprising a~~ wherein said nucleic acid sequence of at least 15 contiguous nucleotides is [[,]] complementary to:

(a) a polynucleotide having a nucleic acid sequence set forth in a SEQ ID NO~~[[,]]~~ selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43 and 45, or a fragment sequence thereof;

(b) a polynucleotide encoding a polypeptide having an amino acid sequence set forth in a SEQ ID NO~~[[,]]~~ selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 and 46, or a fragment sequence thereof;

(c) a polynucleotide encoding a polypeptide variant having at least one mutation selected from the group consisting of one or more amino acid substitution, addition and deletion in an amino acid sequence set forth in a SEQ ID NO~~[[,]]~~ selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 and 46, and having a biological activity;

(d) a polynucleotide ~~of~~ that is an allelic variant of a DNA consisting of a nucleic acid sequence set forth in a SEQ ID NO~~[[,]]~~ selected from the group

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consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43 and 45;

(e) a polynucleotide encoding a species homolog or an ortholog of a polypeptide consisting of an amino acid sequence set forth in a SEQ ID NO[[:]] selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 and 46;

(f) a polynucleotide hybridizing to at least one polynucleotide of any of (a)-(e), and encoding a polypeptide having a biological activity; or

(g) a polynucleotide consisting of a base sequence having at least 70% identity with at least one polynucleotide of (a)-(e) or a complementary sequence thereof, and encoding a polypeptide having a biological activity.

16. (Currently Amended) The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule has ~~An agent causing~~ RNA interference (RNAi) in rice comprising: activity, and wherein said molecule further comprises a polynucleotide complementary to the nucleic acid sequence:

A nucleic acid sequence (A) comprising:

(i) ~~a nucleic acid sequence having at least 15 contiguous nucleotides of a gene encoding a prolamin polypeptide, or~~

(ii) ~~a nucleic acid sequence having at least 70% homology to (i); and a nucleic acid sequence (B) comprising:~~

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~~(iii) a nucleic acid sequence having at least 15 contiguous nucleotides complementary to a gene encoding a prolamin polypeptide, or~~  
~~(iv) a nucleic acid sequence having at least 70% homology to (iii).~~

17 – 18. (Cancelled).

21. (Currently Amended) The nucleic acid molecule according to claim 19, wherein the spacer sequence is ~~comprised~~ between the nucleic acid sequence ~~(A)~~ and the polynucleotide ~~nucleic acid sequence (B)~~.

23. (Currently Amended) A nucleic acid cassette comprising a nucleic acid sequence ~~(B)~~ having antisense or RNA interference activity, comprising:

(i) a nucleic acid sequence having at least 15 contiguous nucleotides complementary to a gene encoding a rice prolamin polypeptide, or

(ii) a nucleic acid sequence having 70% homology to (i),

wherein, when introduced into a rice cell expressing the prolamin polypeptide the nucleic acid cassette is ~~introduced into a rice plant cell expressing the prolamin polypeptide, and the antisense activity of the nucleic acid cassette reduces~~ effective for reducing the amount of expression of the prolamin polypeptide relative to a rice plant into which the nucleic acid cassette was not introduced.



24. (Currently Amended) The nucleic acid cassette according to claim 23, further comprising a promoter that functions in rice operably linked to a nucleic acid sequence encoding a foreign ~~gene~~ protein.

25. (Currently Amended) The nucleic acid cassette according to claim 23, ~~further comprising a nucleic acid sequence (A) comprising:~~

~~(i) a nucleic acid sequence having at least 15 contiguous nucleotides of a gene encoding a prolamin polypeptide, or~~

~~(ii) a nucleic acid sequence having at least 70% homology to (i) wherein said cassette has RNA interference activity, and wherein said cassette further comprises a polynucleotide complementary to the nucleic acid sequence.~~

28. (Currently Amended) The nucleic acid according to claim 26, wherein the spacer sequence is between the nucleic acid sequence ~~(A) and the nucleic acid sequence (B)~~ and the polynucleotide.

29. (Currently Amended) The nucleic acid cassette according to claim 24 or claim 25, further comprising a polynucleotide encoding a signal sequence fused, in frame, to the nucleic acid sequence encoding a foreign protein.

30. (Cancelled)

33. (Cancelled)

34. (Currently Amended) The nucleic acid cassette according to claim ~~33~~ 24 , wherein the promoter sequence is operably linked to both the ~~foreign gene and the nucleic acid (B)~~ nucleic acid sequence encoding the foreign protein and the polynucleotide.

35. (Currently Amended) The nucleic acid cassette according to claim 24, wherein separate promoters are independently operably linked to the ~~foreign gene and the nucleic acid (B)~~ nucleic acid sequence encoding the foreign protein and the polynucleotide.

36. (Currently Amended) The nucleic acid cassette according to claim 35, wherein a first promoter sequence is operably linked to the nucleic acid sequence encoding the foreign protein ~~foreign gene~~, and a second promoter sequence is operably linked to the ~~polynucleotide-nucleic acid sequence (B)~~, and the first and second promoter sequences are not the same ~~different to each other~~.

46. (Currently Amended) The nucleic acid cassette according to claim 33, comprising a polynucleotide encoding a signal sequence in frame between the

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~~foreign gene~~ nucleic acid sequence encoding the foreign protein and the promoter sequence.

49. (Currently Amended) The nucleic acid cassette according to claim 25, further comprising a ~~foreign gene~~ nucleic acid sequence encoding a foreign protein, and the ~~foreign gene~~ is located upstream of both the ~~nucleic acid sequence (A)~~ and the ~~nucleic acid sequence (B)~~ polynucleotide and the nucleic acid complementary to said polynucleotide.

50. (Currently Amended) The nucleic acid cassette according to claim 49 comprising a spacer sequence between the ~~nucleic acid sequence (A)~~ and the ~~nucleic acid sequence (B)~~ polynucleotide and the nucleic acid complementary to said polynucleotide.

51. (Currently Amended) The nucleic acid cassette according to claim 49 comprising an intron sequence between the ~~nucleic acid sequence (A)~~ and the ~~nucleic acid sequence (B)~~ polynucleotide and the nucleic acid complementary to said polynucleotide.

52. (Currently Amended) A method for producing a ~~nucleic acid cassette~~ transgenic rice plant comprising the steps of:

- A) providing [[a]] the nucleic acid cassette according to claim 23;
- B) transforming a rice plant with the nucleic acid cassette; and
- C) selecting a transformed rice plant having ~~an amount of expression of a~~  
~~prolamin that is partially reduced with respect~~ a reduced amount of protein in the  
seeds compared to an untransformed rice plant.

54. (Cancelled)

55. (Currently Amended) The vector according to claim ~~54~~ 53, wherein the  
~~sequence having the promoter activity~~ is a storage protein promoter.

56. (Currently Amended) The vector according to claim 53, wherein the ~~sequence~~  
~~having the promoter activity~~ is a prolamin promoter of ~~prolamin~~.

59. (Currently Amended) The vector according to claim 53, further comprising a  
sequence encoding a foreign protein ~~gene different from the nucleic acid molecule~~  
~~according to claim 1~~ .

60. (Currently Amended) A rice plant cell comprising the nucleic acid molecule  
according to claim 1.

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61. (Currently Amended) The rice plant cell according to claim 60, further comprising a nucleic acid molecule encoding a foreign protein gene ~~different from the nucleic acid molecule according to claim 1.~~

62. (Cancelled)

63. (Currently Amended) The rice plant cell according to claim 60 wherein the plant cell is from [[a]] the same rice variety ~~species, and the species from which the prolamin is derived is the same variant.~~

65. (Currently Amended) The rice plant cell according to claim 60, wherein ~~the species from which the prolamin is derived and the species of the plant are~~ the cell ~~is of a japonica rice and the prolamin is from a japonica rice.~~

66. (Currently Amended) The rice plant cell of claim 60, ~~having the nucleic acid molecule of claim 1 introduced in both alleles thereof~~ wherein the cell is homozygous for the nucleic acid molecule.

77. (Currently Amended) A starch preparation produced from the rice plant cell according to claim 60, wherein said starch preparation comprises said nucleic acid molecule.

78. (Currently Amended) A composition comprising a plant tissue comprising the plant cell according to claim 61, wherein said plant cell comprises said foreign protein ~~a gene product of the foreign gene produced from the rice plant cell according to claim 61.~~

79. (Currently Amended) A method for reducing the amount of an expression ~~amount of a~~ protein in a seed of a rice plant, comprising the steps of:

- A) introducing the nucleic acid molecule of claim 1 into ~~the~~ a rice plant cell;
- B) redifferentiating the cell to produce a transgenic rice plant; and
- C) obtaining a seed from the transgenic rice plant.

80. (Currently Amended) The method according to claim 79, wherein the step of introducing is performed by Agrobacterium-mediated transformation ~~method~~.

83. (Currently Amended) A method for expressing a foreign protein ~~gene~~ in a rice plant seed, comprising the steps of:

- providing the nucleic acid molecule according to Claim 1;
- providing a nucleic acid encoding the foreign protein ~~gene~~ ;
- introducing the nucleic acid molecule according to Claim 1 and the nucleic acid molecule encoding the foreign protein ~~gene~~ into a cell of the rice plant;

redifferentiating the cell to produce a transgenic rice plants; and  
obtaining a seed from the transgenic rice plant.

84. (Currently Amended) The method according to claim 83, wherein the step of introducing is performed by Agrobacterium-mediated transformation ~~method~~.

87. (Currently Amended) The method according to claim 83, further comprising the step of separating ~~a gene product of the foreign gene~~ the foreign protein from the seed.

88-91. (Cancelled)

***Allowable Subject Matter***

5) Claims 1, 2, 4-9, 11, 12, 16, 19-21, 23-29, 31, 32, 34-38, 40-53, 55-61, 63, 65-67, and 77-87 are allowed and are renumbered as claims 1-64, respectively.

### EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

6) The following is an examiner's statement of reasons for allowance: The Applicant has presented persuasive arguments regarding unexpected results from the inhibition of expression of prolamin genes in rice (see pages 17-19 of the response filed on Jan. 21, 2010). The prior art teaches that inhibition of glutelin does not result in a substantial reduction in protein in the seed, because the expression of other seed proteins is upregulated when the glutelin expression is downregulated. Surprisingly, when the Applicant's produced transgenic rice plants with an antisense construct effective for inhibition of expression of prolamins, several prolamin genes were downregulated, and there was not corresponding increase in expression of the other seed storage proteins (see Table 1 on page 128 of the specification). This showing of an unexpected results overcomes the Examiner's position that inhibition of one storage protein is obvious over inhibition of another storage protein, because the Applicant has shown that inhibition of expression of prolamins in rice results in a significant reduction in the total seed protein content which is substantially different from the result achieved by inhibition of expression of glutelin in rice.

Because the Applicant's data show an inhibition of expression of three different prolamin genes, it would be expected that their surprising results could be extended to inhibition of expression of any prolamin gene in rice. The prolamin gene family in rice is well-known, and there are many known variants in different



varieties, cultivars, and ecotypes of rice. It would be expected that one could achieve reduced total protein content in rice seeds by inhibition of expression of any one of the prolamin genes in rice.

7) Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638